avma

action *against* medical accidents

An organisation losing its memory?

Patient safety alerts: implementation, monitoring and regulation in England

A report by Action against Medical Accidents

Dr David Cousins

January 2020

Contents

List of tables and figures

About the author

Dr David Cousins is an independent safe medication practice consultant; former head of safe medication practice, National Patient Safety Agency and NHS England. David is a voluntary advisor to Action against Medical Accidents (AvMA – the national charity for patient safety and justice).

An organisation losing its memory?
Patient safety alerts: implementation, monitoring and regulation in England

Executive summary

Introduction

Action against Medical Accidents (AvMA) has been concerned for a long time over the effectiveness of the system to protect patients from patient safety incidents involving known risks published in patient safety alerts. Using Freedom of Information (FOI) requests to NHS organisations in 2010, 2011 and 2014, AvMA identified poor implementation and governance of patient safety alerts in some NHS organisations in England and a poor oversight of the implementation of alert guidance by the Care Quality Commission (CQC) and NHS England. In 2010 there were 2,124 instances of non-compliance, this had dropped to 141 instances of non-compliance in 2014, however the number of patient safety alerts that were published had also reduced.

In this study we used the patient safety compliance data published by NHS Improvement in March 2019 and subsequently in July 2019. We made FOI requests to all the trusts listed in the March 2019 report as non-compliant with patient safety alerts past their deadline date for implementation. We also made FOI requests to the CQC and NHS Improvement and asked questions about what actions they had taken to support and check the implementation of patient safety guidance.

Results

From the NHS Improvement reports, there were 44 trusts and 64 instances of non-compliance past the implementation deadline date for patient safety alerts in March 2019. There were 18 instances where the compliance deadlines were between 2016 and 2017.

There were 11 alerts which had not been signalled with full compliance. One alert (*Resources to support safer care for patients at risk of autonomic dysreflexia*) with a deadline date in January 2019 accounted for 37 instances (58%) of the non-compliance in March 2019. This number significantly reduced by July 2019 however, there were still 19 instances of non-compliance with this single alert and 16 instances of non-compliance with eight other alerts. In July 2019, 26 NHS trusts remained non-compliant with one or more alerts.

We requested FOI responses from the 44 NHS trusts identified as non-compliant by NHS Improvement. We received responses from 43 trusts (98%). One trust did not provide responses to our questions.

Qualitative analysis of FOI responses from the NHS indicated that processes were reported to be in place to implement these alerts, including internal distribution of copies of the alert, risk assessment, review, appointment of a clinical lead, development of an action plan, audit and formal sign-off appear to be in place.

There were a variety of reasons presented to explain the delay in implementing alerts. These included the absence of relevant national standards and codes of practice. The need for complex local actions such as comprehensive literature review, production of guidelines, policies and training materials for alerts. Also, capacity and governance issues associated with the absence or change of staff who had been assigned to oversee implementation, trust

merger, and administrative error. This indicated insufficient oversight of the implementation process. Additional time was required to develop and undertake audits to determine that implemented actions were in operation. Finally, the requirement to procure systems and products to comply with alert guidance also delayed implementation. Some trusts also changed the status of alerts where compliance had previously signalled, as non-compliant, on the basis of new patient safety incidents or re-audit data.

There were 10 patient safety incidents, concerning risks identified in alerts, reported from six trusts who were non-compliant, who also responded to the FOI request. Little further information was provided but the outcomes indicated these incidents had caused 'minor harm'.

Thirteen trusts indicated the need for further improvements to the trust's internal processes to implement patient safety alerts and these had either been completed or were underway.

NHS Improvement refused to provide any information requested in AvMA's FOI request citing an exemption because of the cost of providing the information. In spite of further requests, no response was received from NHS Improvement to questions concerning actions that they had taken with trusts who had not signalled compliance with patient safety alert guidance after the target date.

CQC responded to say that compliance with alerts by NHS trusts is reviewed as part of the regulatory monitoring and inspection cycle, CQC insight indicators, responses to provider information requests and inspection of provider sites. The CQC does not have a central database that enables interrogation of all their actions against individual trusts. This information is held locally with each inspection team.

Concerns and recommendations

Data collected in our study indicates that the governance arrangements for the implementation of patient safety alert guidance within many individual trusts is still poor and the introduction of safer practice can be significantly delayed. Many of the trusts responding to the FOI requests indicated that they were in the process of improving internal systems for overseeing the implementation of patient safety alerts.

The role and responsibility of national organisations to oversee the implementation of these alerts was unclear and ineffective in some cases.

Review of 2019 publications, including the NHS Patient Safety Strategy, a Central Alerting System Alert announcing a new format for patient safety alerts and summary criteria for the management and creation of national patient safety alerts, has identified additional important concerns and recommendations:

CONCERN 1

It is unclear whether the NHS is expected to implement (and to continue to implement) all patient safety alerts that have been published. There is also lack of clarity over the remit of the patient safety team and the national reporting service in NHS Improvement and the criteria required to trigger the publication of a patient safety alert. How are risks managed after a patient safety alert has been issued, and reports of death and serious harm continue to be received months and years after the date the alert should have been implemented?

RECOMMENDATION 1

More information should be published by NHS Improvement concerning:

1. Implementation requirements of new format national patient safety alerts and previous format patient safety alerts published by NHS Improvement, NHS England and the National Patient Safety Agency.

2. The current statutory requirements and scope of the patient safety team and National Reporting and Learning System. If this only includes new/unrecognised risks, when did this change and which organisation is now responsible nationally for publishing detailed data to identify and co-ordinate action on known/wicked risks?

3. The threshold required for the publication of a patient safety alert concerning a specific risk has been defined by the Patient Safety Alert Advisory Committee as 'more likely than not, one or more potentially avoidable deaths or disability in healthcare in England each year'. The National Reporting and Learning System receives incident reports about dozens of risks that exceed this threshold each year. What criteria are used to further select the few risks chosen for patient safety alerts that are published by NHS Improvement?

4. Further clarity is required on how risks will be managed once a patient safety alert has been published and the risk can no longer be classified as 'new or unrecognised'. Will additional patient safety alerts be issued concerning the same risk, if evidence of harm continues to be reported? What other action will be taken to better manage these risks?

CONCERN 2

There is insufficient transparency concerning the identity of all major risks, including known/wicked risks, to patient safety reported to the NHS National Reporting and Learning System (NRLS).

RECOMMENDATION 2

The NRLS (and any successor systems) should regularly publish detailed information on all major risks identified by the reporting system at a suitable level for learning. This data should be cross referenced to recommended safeguards in practice (guidance from patient safety alerts) intended to minimise harm. Collectively this guidance forms national standards for patient safety.

CONCERN 3

There have been 137 patient safety alerts published in England since 2002. Many of these alerts identified and provided guidance on major risks from the NRLS. Some 75 of the alerts have now been archived and the NHS patient safety strategy raises uncertainty over the status of all previous alerts concerning risks now described as known/wicked risks. The new national patient safety improvement programme only addresses a very small number of these risks. How will risks outside the safety improvement programme be managed?

RECOMMENDATIONS 3

The original remit for patient safety alerts should be reinstated. Alerts should be used to communicate all types of risk to patient safety, not just new and unrecognised risks. All alerts should once again contain materials to support NHS organisations implement guidance.

All previous patient safety alerts should be regularly reviewed, linked to current NRLS data, other evidence and guidance. NHS Improvement should publish updated alerts to assist the NHS to continue to address these known risks. Information in these new alerts should be used to provide national standards for patient safety to prevent 'post code patient safety'.

Whilst the rate of compliance with patient safety alerts has improved since our previous reports, there still appears to be inadequate monitoring and regulation of compliance of primary as well as secondary and community sectors at national level.

A more robust and proactive system of monitoring and regulating compliance with patient safety alerts in both primary, secondary and community sectors is required. The CQC should maintain a central database on alert compliance and actions they are taking to ensure compliance. The CQC (or NHS Improvement) should proactively 'chase' trusts and provider organisations who are late in complying and CQC should be seen take regulatory action over non-compliance long past a deadline or non-compliance with multiple patient safety alerts.

Background

The National Health Service was recommended to be a 'organisation with a memory' in a report with same name published by the Chief Medical Officer in 2000.[1] The report revealed that too many patients were being harmed when things went wrong with medical interventions and that these harms could have been avoided had the lessons of past experience been properly learned. The report recommended steps to be taken to ensure that the NHS learns from its experiences, so that the risk of avoidable harm to patients is minimised. There were four key areas to be developed by the NHS:

1. *Unified mechanisms for reporting and analysis when things go wrong;*

2. *A more open culture, in which errors or service failures can be reported and discussed;*

3. *Mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice;*

4. *A much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.*

This report from AvMA concerns key area three.

The NHS National Reporting and Learning System (NRLS) was established in 2003 as a central database of patient safety incident reports.[2] Since 2003 the culture of reporting incidents to improve safety in healthcare has developed to the extent that over 2 million patient safety incidents are reported to the NRLS each year.[3]

The Central Alerting System (CAS) is a web-based cascading system introduced in 2008 for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care.[4]

The system requires NHS organisations to respond to confirm that they have received the alert, whether any action is required and when they commence and have completed the implementation of the alert guidance or other actions.

Each month NHS Improvement posts a report on their website, of those organisations who have not completed actions recommended in patient safety alerts by the specified deadline date.[5]

It is the role of the CQC when inspecting NHS organisations in England to check on the implementation of patient safety alerts as part of their regular inspection programme.[6]

AvMA has been concerned for a long time over the effectiveness of this system to protect patients from patient safety incidents involving these known risks published in patient safety alerts.

Using Freedom of Information (FOI) requests to NHS organisations in 2010, 2011 and 2014, AvMA identified poor implementation and governance of patient safety alerts in some NHS organisations in England and a poor oversight of the implementation of alert guidance by the CQC and NHS England.[7]

In our previous reports we identified the following number of instances of non-compliance with patient safety alert guidance by the target date for implementation:

- 2,124 instances of non-compliance in February 2010,

- 455 instances of non-compliance in August 2011,

- 141 instances of non-compliance in January 2014.

There were several trusts who had not complied with three or more patient safety alerts and several cases where the deadline had been exceeded by over five years.

In this study we used the patient safety compliance data published by NHS Improvement in March 2019[5] and subsequently in July 2019. We made FOI requests to all the trusts listed in the March 2019 report as non-compliant with patient safety alerts past their target date for implementation. We asked the following questions:

1. What action has the trust taken to implement the alert guidance by the completion deadline?

2. Why has implementation of the alert guidance not occurred by the completion deadline?

3. When will the trust signal full compliance with the alert guidance?

4. Have any patient safety incidents concerning the topic of the non-compliant alert been reported in your trust since the alert was published?

5. How will the process be improved in the future to ensure that patient safety alerts will be implemented by the completion deadline?

We compiled FOI responses and compared compliance data published by NHS Improvement in March 2019 and then in July 2019, after the trusts had responded to our FOI request.[5]

We also made FOI requests to the CQC and NHS Improvement and asked questions about what actions they had taken to support and check the implementation of patient safety guidance.

Results

Quantitative results

Data published by NHS Improvement on compliance with NHS patient safety reports in March 2019 and after we had received responses to FOI requests in July 2019 is shown in Table 1.

There were 44 trusts who had not signalled compliance by the deadline date with one or more patient safety alert in March 2019.

There were 64 instances of non-compliance in March 2019. The number of instances of non-compliance reduced to 35 in July 2019 following our FOI requests. Dartford and Gravesham NHS Hospital Trust had the most (five) instances of non-compliance in March 2019 and in July 2019.

A comparison of the instances of non-compliances with patient safety alerts by deadline year is shown in Table 2. There were 18 instances where the compliance deadlines were 2016 or 2017 reported in March 2019. This reduced to 11 in July 2019. One NHS Trust changed the status of an alert from compliant to non-compliant between March and July 2019.

Table 1: Data from NHS Improvement reports on instances of NHS trust non-compliance with patient safety alerts

Data point description	Data published in March 2019	Data published in July 2019
Instances where NHS trusts had not signalled that they had fully complied with the patient safety alert guidance by the deadline date	64	35 *(29 closed from March 2019)*
Individual NHS trusts that had not signalled that they had fully complied with the patient safety alert guidance by the deadline date	44	26
The NHS trust with the largest number of safety alerts that had not been fully complied with by the deadline date	Dartford and Gravesham 5 alerts Wye Valley 4 alerts	Dartford and Gravesham 5 alerts

Table 2: Data from NHS Improvement reports on instances of non-compliance with patient safety alerts by compliance deadline year

Compliance deadline year	2019	2018	2017	2016	2014
Instances of non-compliance of patient safety alerts by deadline year in March 2019	37	9	12	6	0
Instances of non-compliance of patient safety alerts by deadline year in July 2019	19	5	6	4	1

The number of instances of non-compliance by patient safety alert topic is shown in Table 3. There were 11 alerts which had not been signalled with full compliance. One alert (*Resources to support safer care for patients at risk of autonomic dysreflexia*)[8] with a deadline date in January 2019 accounted for 37 (58%) of the non-compliance in March 2019. Non-compliance reduced by July 2019, however there were still 19 instances of non-compliance with this single alert.

We requested FOI responses from the 44 NHS trusts identified as non-complaint by NHS Improvement. We received responses from 43 (98%) trusts. One Trust (Southend NHS Trust) did not provide responses to our FOI requests.

Qualitative data from FOI responses from NHS trusts

A summary of the qualitative analysis of the FOI responses received by AvMA is shown below:

QUESTION 1

What action has the trust taken to implement the alert guidance by the completion deadline?

Summary of responses: Processes in place included internal distribution of copies of the alert, risk assessment/review, appointment of a clinical lead, development of an action plan, audit and formal sign off appear to be in place. How well these processes are working is covered in response summaries to the other questions.

Table 3: Data from NHS Improvement reports on instances of non-compliance by individual patient safety alert

Patient safety alert title	Deadline date	Non-compliant in March 2019	Non-compliant in July 2019
Resources to support safer care for patients at risk of autonomic dysreflexia	25.1.2019	37	19
Confirming removal or flushing of lines and cannulae after procedures	9.8.2018	7	4
Supporting the introduction of the national safety standards for invasive procedures	14.9.2016	6	4
Restricted use of open systems for injectable medication	7.9.2017	4	2
Resources to support safe transition from the luer connector to NRFit for intrathecal and epidural procedures, and delivery of regional blocks	11.12.2017	3	2
Nasogastric tube misplacement: continuing risk of death and severe harm	21.4.2017	2	0
Risk of death or severe harm from inadvertent intravenous administration of solid organ perfusion fluids	31.5.2018	1	0
Reducing the risk of oxygen tubing being connected to air flowmeters	4.7.2017	1	1
Resources to support the safe adoption of the revised national early warning score (NEWS2)	21.6.2018	1	1
Resources to support the safety of girls and women who are being treated with valproate	6.10.2017	1	1
Resources to support safer care of the deteriorating patient (adults and children)	31.1.2017	1	0
Non-luer spinal (intrathecal) devices for chemotherapy	20.08.2014	0	1
Totals		**64**	**35**

Examples responses to question 1

'The governance team distributed this alert to members of the clinical management team and clinical leads.'

'Risk assessment completed.'

'A trust lead is appointed to take forward the recommendations of the alert.'

'The trust has an ongoing action plan in place which addresses the areas outlined in the alert and requires adequate time to be implemented thoroughly within the organisation.'

'The trust is finalising an audit to ensure compliance.'

'As part of the actions to implement the alert, a new bowel care policy has been produced and is currently in its final phases of sign off.'

QUESTION 2

Reasons for the delay in implementing patient safety alert guidance

Summary of responses: There were a variety of reasons presented to explain the delay in implementing alerts. These included the absence of relevant national standards and codes of practice. The need for complex local actions such as comprehensive literature review, production of guidelines, policies and

training materials for alerts. Also, capacity and governance issues associated with the absence or change of staff who had been assigned to oversee implementation, trust merger, and administrative errors (indicating insufficient oversight of the implementation process). Additional time required to develop and undertake audits to determine that implemented actions were in operation.

One trust determined not to implement the guidance for a specific procedure and to continue previous practice and enter the risk in the trust risk register. The requirement to procure systems and products to comply with alert guidance was another reason for delay. In particular, the delay in manufacturers providing non-Luer versions of epidural devices for use. It is curious that only one trust has indicated that this alert has not been fully implemented, as manufacturers have not provided all epidural equipment to enable any trust to 'fully' comply. This is correct, not all epidural products are available with non-Luer connectors in the UK. How have other trusts been able to sign off on this alert?

NHS trusts also changed the status of an alert, to 'non-compliant', which they had previously signalled as compliant, following patient safety incidents (including never events) and re-audit.

Example responses to question 2

'Review of existing processes and controls, development of further control measures where required, agreement on roles and responsibilities of staff groups and of monitoring compliance through a relevant committee or group, a review of training needs and the development of policy, all of which, in addition to time spent undertaking suitable and sufficient consultation with relevant multi-disciplinary teams and the use of existing governance frameworks in place, would not have been properly achieved within the six month timeframe that was originally set within this alert.'

'The delay in closing the alert related to one This alert was considered by the Central Alerting System (CAS) lead to be of a complex nature due to the requirement to produce a guideline and support reference document. The lead undertook a comprehensive literature review to compliment and update the trust existing guideline. This literature review took longer than expected due to this being performed in addition to the lead's clinical responsibilities.'

'Compliance with this alert is virtually complete, but still needs a guideline so teams have a resource should they need to develop safety checklists for future interventional procedures. This will be completed in 2019.'

'It has taken some time to align clinical guidelines across all trust sites.'

'Reasons for delay: available resources, capacity, need for business case approval, reliance on external guidance, codes of practice or standard e.g. we cannot progress an action until a national code of practice is published; however, there is a delay in the document being published and made available to the trust.'

'The merger of the organisation has contributed to the delay in achieving the deadline for this patient safety alert as this has meant integrating the documentation as well as including the changes required.'

'Changes of staffing within quality team.'

'An administrative error meant these were not distributed and acted upon.'

'The previous lead for this alert has left the trust but we have recently appointed a new nurse clinical lead for this area and she will be progressing work on this alert.'

'The alert was circulated but the Central Alerting System (CAS) was not updated to reflect the action taken as the member of staff responsible for updating the CAS took unplanned leave.'

'Completion of all actions related to this alert was predominantly reliant on the procurement and implementation of the replacement for the electronic clinical system (ECS), which is due within the next 18 months. In light of the anticipated time taken to procure the new system it was agreed that the current system would be upgraded. The time taken to implement this resulted in a delay in the delivery of the entire alert.'

'There is currently inadequate audit confirmation to demonstrate full compliance. Specific procedure where the specialty team had undertaken a thorough risk/benefit.'

'Full product not available from the manufacturer until September 2019.'

'Assessment with consensus that the procedure with (specific mitigations) could continue to employ an open system.'

'We originally declared compliance with this alert because it was felt all work had been completed and communicated to staff. However, in light of three never events relating to patients briefly connected to air rather than oxygen (no harm to patients), the trust decided to take an honest approach and declare non-compliance. Since this time the trust has invested in nebulisers and these are being rolled out across the trust to prevent this never event occurring. This is expected to be completed imminently as nurses are trained and air outlets are going to be capped. The trust will then declare full compliance.'

QUESTION 3

Expected compliance date with outstanding alert(s)

Summary of responses: These were incomplete, and there were ambiguous responses to this question. It was determined that by looking at trust compliance status in the NHS Improvement alert compliance report published in July 2019 would provide better data on action that had been taken following the FOI requests. Forty five percent of the instances of non-compliance with alerts identified in March 2019 in FOI requests were closed by July 2019. There were 35 instances where alerts identified in FOI requests remained open.

QUESTION 4

Have any patient safety incidents concerning the topic of the non-compliant alert been reported in your trust since the alert was published?

Summary of responses: Six trusts reported that a total of ten patient safety incident reports had been received involving risks identified in Patient Safety Alerts where full compliance by the trust had not been reported to the Central Alerting System (CAS). Limited information about these incidents was shared, see below:

Trust 1. A patient safety incident report involving risks identified by the patient safety alert *'Supporting the introduction of the national standard for invasive procedures'* issued in September 2015 with an implementation date of September 2016. Comment from the trust *'however, local LOCCSIP policy was in place at the time'*. No details on clinical outcome were shared.

Trust 2. Two patient safety incidents reports involving risks identified by the patient safety alert *'Confirming removal of intravenous flushing lines and cannulae'* issued in November 2017 with an implementation date of August 2018 .The clinical outcome that was reported was *'no harm'*.

Trust 3. Two patient incident reports involving risks identified by the patient safety alert *'Nasogastric tube misplacement: continuing risk of death and severe harm'* issued in July 2016 with an implementation date of April 2017. The clinical outcome reported was *'minor severities'*.

Trust 4. One patient safety incident report involving risks identified by the patient safety alert *'Nasogastric tube misplacement: continuing risk of death and severe harm'* issued in July 2016 with an implementation date of April 2017. No details on clinical outcome were shared.

Trust 5. A patient safety incident report involving risks identified by the patient safety alert *'Supporting the introduction of the national standard for invasive procedures'*, issued in September 2015 with an implementation date of September 2016. No further information was provided.

Trust 6. Three 'never events involving risks identified in the patient safety alert *'Reducing the risk of oxygen tubing being connected to air flow meters'* issued in October 2016 with an implementation date of July 2017. The trusts said that these have been investigated and there was no patient harm as a result of these incidents.

QUESTION 5

How will the process be improved in the future to ensure that patient safety alerts will be implemented by the completion deadline?

Summary of responses: Thirteen trusts indicated the need for further improvements to trust's internal processes to implement patient safety alerts were required and these improvements had either been completed or were underway.

'A review of process has been underway during the last few months after it was identified that policy was insufficiently robust in terms of ownership and oversight; and that management capacity was insufficient to manage the process as effectively as we would like. A review of policy is almost complete and due to be presented to the patient safety committee in June for approval. Education, sub-committee responsibilities and risk management liaison feature as part of the review.'

'This was a human error and the process has been tightened to prevent further issues.'

'There is a CAS improvement plan being implemented within the trust to maintain performance with patient safety alerts. This is being led by the clinical risk manager.'

'National communication from NHS Improvement has indicated premature closure of alerts in the past and this has been an issue across the NHS. Therefore, the trust's approach to patient safety alerts is for all aspects of the requirement to be fully implemented, no matter how minor, before closing the alert.'

'The process for managing alerts has been incorporated into the trust's governance processes that ensure there is monthly review and oversight of all alerts and compliance with alerts. Business continuity has been developed to support resilience during unplanned staff absence.'

'We have recently streamlined the governance process as regards to managing patient safety alerts. The internal audit in relation to the management of the safety alerts has recently been completed and several recommendations have been made which are now being implemented. The compliance and progress implementing safety alerts are being reported to the trust clinical governance group and quality board.'

'We have faced some internal challenges due to our previous patient safety manager leaving the trust and further vacancies and work pressures within the team. A business case has been developed and submitted which if agreed will provide resilience to the team which would ensure that timeframes would be more achievable.'

'A new process for NHS patient safety alerts is being implemented at the trust to ensure that trust committees have increased visibility

of the alerts. This process will also support commissioning and closure by the senior executive team.'

Response to FOI request from NHS Improvement

NHS Improvement refused to provide any information requested in AvMA's FOI request citing an exemption because of the cost of providing the information. In spite of further requests, no response was received from NHS Improvement to questions concerning actions that they had taken with trusts who had not signalled compliance with patient safety alert guidance after the target implementation date..

Response to FOI request from the Care Quality Commission (CQC)

Response summary: Compliance with alerts by NHS trusts are reviewed by the CQC as part of the regulatory monitoring and inspection cycle, CQC insight indicators, responses to provider information requests and inspection of provider sites.

The CQC does not have a central database that enables interrogation of all of the actions (including those concerned against individual trusts). This information is held locally with each inspection team.

QUESTION 1

Any action which CQC has taken concerning NHS trusts who have not signalled their compliance with the alert by the deadline for completion

Response:

'In accordance with section 1(1) of the Freedom of Information Act A we are able to confirm that CQC does hold recorded information in relation to this matter, however we consider that this information is exempt from disclosure under section 31 of the Act because the potential prejudice to our regulatory function. This exemption is explained in detail below.

'We do not have a central database that would allow us to interrogate all of the actions we have taken against individual trusts. This information would be held locally with each inspection team. However, we may be able to identify some information where specific enforcement action has been taken.

'Our enforcement team has advised that they are currently aware of one case relating to patient safety alert compliance, however, as this is an ongoing matter we cannot provide any further information at this point in time without prejudicing the outcome of this process.'

QUESTION 2

To what degree is compliance with patient safety alerts an integral part of CQC inspection of healthcare providers?

Response:

'NHS trust compliance with patient safety alerts (PSA) is reviewed at various point throughout the regulatory monitoring and inspection cycle, and this is largely covered under key lines of enquiry (KLOE) S6.5 in the safe key question (How effective are the arrangements to respond to relevant external safety alerts, recalls, inquiries, investigations or reviews).

'CQC insight contains three trust-wide indicators related to the Central Alerting System (CAS). All three indicators give the latest performance, performance against the national comparison and a 'change over time' marker:

1. CAS alerts closed late in the preceding 12 months
2. CAS alerts not closed by the trust in the preceding 12 months
3. CAS alerts not closed by the trust more than 12 months before.

'CQC insight also includes indicators for never events, which may be:

- linked to patient safety alerts and/or,
- indicators and trends from CAS alerts will be discussed as required in the (at least quarterly) relationship management meetings with trusts.

'The routine provider information request (PIR) sent to trusts approximately annually also includes questions relevant to patient safety alerts:

- Details of whether a CAS alerts officer / administrator or other
- CAS related role is in post
- Whether the trust has audited safety alert compliance in the last 12 months. If so, the top themes that resulted from the audit.'

Inspection

'Inspection focuses on systems and process for the implementation of PSAs, but there are some examples of specific patient safety alerts featured in our inspection frameworks (for example the emergency and urgent care service for NHS ambulance trusts, which references NHS England's 2015 PSA from delayed updates to ambulance dispatch and satellite navigation systems).

'Our inspection of 'well-led' issues at trust level may include interviews with the non-executive director (NED) responsible for safety and risk, as well as CAS officer / administrator. Both interviews probe the systems and processes for implementation of alerts.'

New developments

'At the request of the former Secretary of State for Health, we are in the process of strengthening our assessment of the implementation of patient safety alerts. This links to wider projects to improve the consistency and quality of the patient safety alerts that are issued, with the establishment of a national patient safety alert committee (NaPSAC) – more details on that can be found on the NHS Improvement website. Those alerts that are identified as 'safety critical' will form a suite of alerts from which CQC can select to inspect, to test whether trusts have robust systems for the receipt and implementation for alerts. The CQC report 'opening the door to change' reinforced the need for the NaPSAC to 'oversee a standardised patient safety alert system that aligns the processes and outputs of all bodies and teams that issue alerts, and made sure that they set out clear and effective actions that providers must take on safety critical issues.'[9]

QUESTION 3

What action does the CQC take if it is found during the inspection process that an NHS trust or health care provider organisation is unable to demonstrate that it has implemented one or more patient safety alerts by the deadline for completion?

Response:

'Page 30/31 of the health assessment framework shows how the systems and processes for, and compliance with, patient safety alerts are reflected in the ratings characteristics.[10]

'A key aspect of the new developments described above is to ensure that CQC uses its enforcement powers robustly and consistently if trusts do not have effective processes for alert implementation. Failure to implement would result in a breach of regulation 12: safe care and treatment.'[11]

QUESTION 4

What action does the CQC take if it is found that a trust or health care provider repeatedly does not implement patient safety alerts in a timely fashion?

Response

'Please refer to our response to question 3.'

Discussion, concerns and recommendations

Data collected in our study indicates that the governance arrangements for the implementation of patient safety alert guidance within many individual trusts is still poor and improvements to practice can be significantly delayed, for example the absence or change of staff allocated to oversee this work or administrative errors. Insufficient supporting information and national standards linked to the alerts requiring clinical leads and others in every trust to undertake literature reviews, develop local protocols, guidelines training materials and monitoring tools, appears to be an inefficient use of resources when more could be done centrally and then adapted for use locally.

Many of the trusts responding to the FOI requests indicated that they were in the process of improving internal systems for overseeing the implementation of patient safety alerts.

The role and responsibility of national organisations to oversee the implementation of these alerts was unclear and ineffective in some cases.

From information in the public domain, the patient safety team in NHS Improvement only publish data on compliance with the patient safety alerts from the CAS database each month. No other action taken by NHS Improvement to support organisations that have not implemented the guidance by the target date is available in the public domain.

It is of concern that the CQC does not have a central database that enables interrogation of all of the actions (including those concerned against individual trusts). This information is held locally with each inspection team. With these processes still in place trusts can still signal 'non-compliance' years after alert deadlines for completion.

It is acknowledged that the number of instances of non-compliance with patient safety alerts has considerably reduced from 2,124 instances of non-compliance in February 2010 to 64 instances in March 2019. However, the number of patient safety alerts has also reduced significantly (Figure 1), which is an important finding and will be discussed later.

There have been three recent national reports published relevant to this study that need to be included in the discussion of our findings.

REPORT 1

The HSIB national investigation into wrong route errors

The Healthcare Safety Investigation Branch (HSIB) published a national investigation report on '*the inadvertent administration of a oral liquid medicine into a vein*' in April 2019.[12] A patient safety alert on this topic was published by the National Patient Safety Agency in 2007[13] and the risk was also identified as a never event by the NHS. In the report the HSIB also reviewed the broader topic of implementation of patient safety alerts.

As part of the investigation the HSIB contacted the NRLS to obtain details of medication incident reports between 2013-2018. The information included sub-category details. Of the 1,048,594 medication incidents reported, there were 14,140 incidents of wrong route error. Over the five-year period the sub-category 'wrong route error' had the largest percentage increase in reporting. The number of reports of this type increased by 23% from 2016/17 to 2017/18.

This large increase was not identified and communicated to the NHS by the NRLS or NHS Improvement and in fact the only action taken during 2017/18 was to remove the original patient safety alert on wrong route errors from the NHS Improvement patient safety web site and archive it to the national

Figure 1: The number of published patient safety alerts in England per year 2002 – August 2019
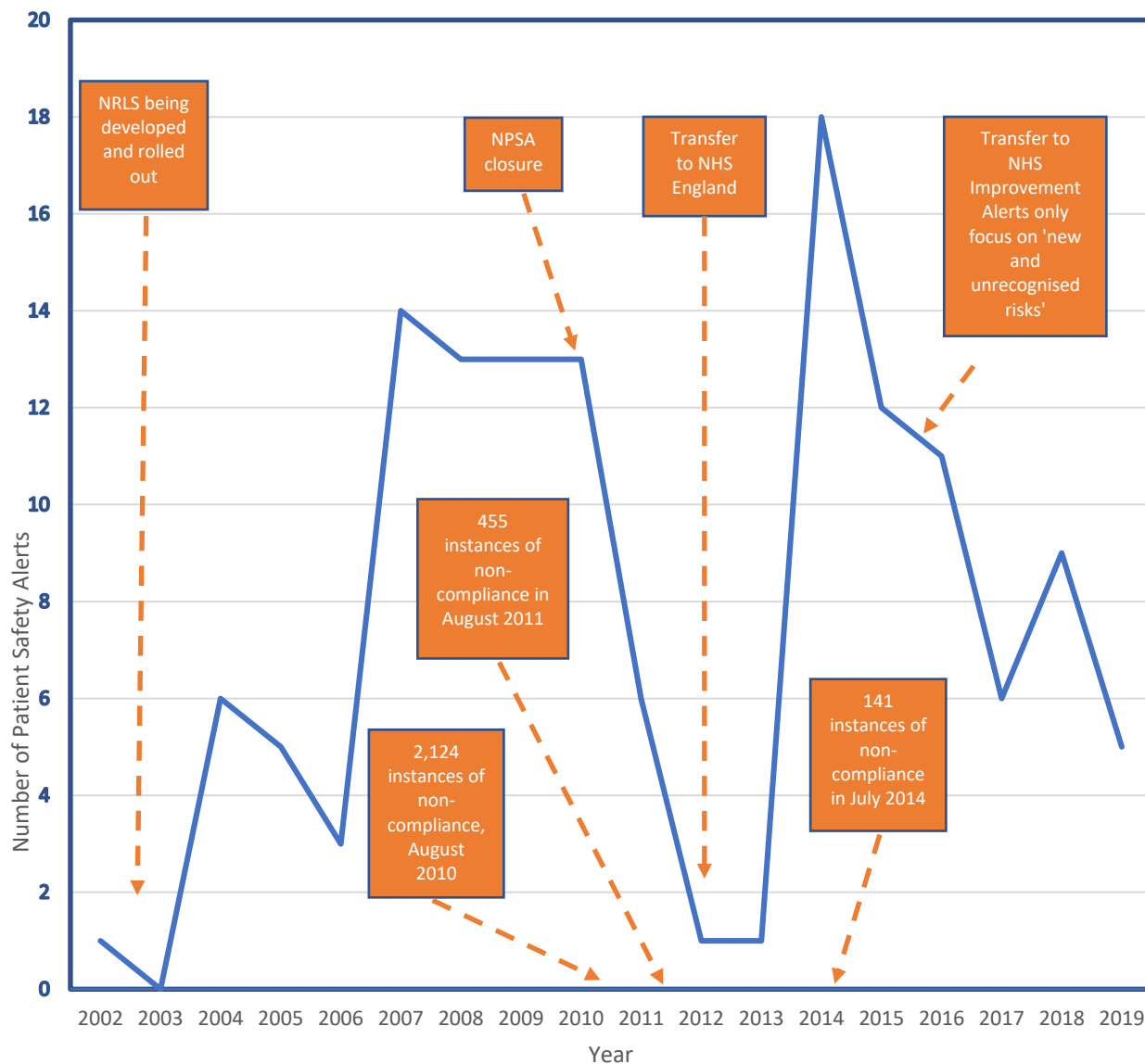
archive website[13] (along with other NPSA patient safety publications) and added the following cautionary note:

'*NPSA alerts were only updated to reflect changes in current safety knowledge or clinical care until the point their 'action compete' date was reached. Some of these 'action complete' dates for NPSA alerts, safety notices and rapid response reports were over 15 years ago. No NPSA publications have been updated since the closure of the agency in 2012, with the exception of key actions still relevant to the never events policy and framework.*'[14]

Many of the findings from this study are supported by findings in the HSIB report, as can be seen in the follow extracts.

Extracts from the HSIB investigation report

'*Monitoring and evaluation of national patient safety actions, for example patient safety alerts and design and procurement of new equipment, is limited and where implemented is inconsistent, making it difficult to track progress and plan for continual learning for improvement*' (section 7.4).[12]

'*Many organisations, including NHS Improvement, Health Education England, royal colleges and professional regulation play a substantive role in medicines safety. However, the current system is confused and complex with a lack of clarity of the roles of these organisations and their responsibilities for system wide implementation of messages concerning safety. This is despite the*

enthusiasm and commitment of the healthcare professionals and national bodies the investigation team consulted' (section 6.20).[12]

'Recommendations identified in previous publications on improving medicines safety, dating back over a decade, appear to be challenging to implement and remain outstanding' (section 6.22).[12]

'Guidance and standards on prescribing, preparation, checking and administration of medicines is fragmented and divided between a range of professional and NHS regulatory bodies' (section 6.23).[12]

'Local medication policies and guidelines do not follow a consistent core framework linking the various strands of medicines use within the NHS' (section 6.24).[12]

One of the key recommendations for the HSIB report is as follows:

'Recommendation 2019/028:

It is recommended that NHS Improvement, through the national patient safety alert committee, set standards for all issuers of patient safety alerts which make clear that alert issuers should assess for unintended consequences of the actions in the alert, the effectiveness of barriers created by these actions, and provide appropriate advice for providers on implementation, include ongoing monitoring.'[12]

Under the section safety actions carried out and/or in progress HSIB noted that NHS Improvement is working towards a national medication safety programme in April (As part of the national patient safety improvement programme) This will be discussed later but this national programme does not include any work on wrong route medicine errors and other known/wicked risks previously identified in patient safety alerts including those identified as 'never events'.

CQC 'opening the door to change'

The CQC did refer us to their report entitled *'Opening the door to change. NHS safety culture and the need for transformation'*, published in December 2018[9]. The report concerns the following:

'Never events are serious incidents that are considered to be wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. However, never events continue to happen there were 468 incidents provisionally classified as never events between 1 April 2017 and 31 March 2018'.[9]

In the report the CQC examined the underlying issues in NHS trusts that contribute to the occurrence of never events and the learning that can be applied to wider safety issues. They did this by visiting 18 NHS trusts, carrying out one-to-one interviews, visiting different services and reviewing policies and procedures. Holding forums and workshops with patient representatives, people from the NHS, other healthcare organisations and other industries, and safety and human factors experts. Focus groups with frontline staff were held and information from arm's length bodies about their role in patient safety was requested. The CQC spoke to many experts as part of this thematic review. A key focus of our review was to understand the approach to safety of other safety-critical industries, such as aviation, nuclear, and fire and rescue.

Report findings included the following:

'Patient safety alerts are generally viewed as an effective way to disseminate safety guidance to trusts, the context in which they are landing creates numerous challenges for trusts.[9]

'With the competing pressures on staff due to high workloads, implementing patient safety alerts can be seen as just one more thing to do,

and can lead to staff taking a mechanistic and siloed approach to implementation. This might mean passing responsibility for implementing alerts to multiple individuals, rather than having a system in place to coordinate implementation. This can lead to many adaptations of the same piece of guidance.

'Different approaches to governance mean that processes are not in place to drive or monitor progress effectively, and too much reliance is placed on the individuals delegated the task of implementing alerts. In addition, boards are not consistently prioritising meaningful discussions about never events and associated safety alerts.

'Leadership styles and hierarchies can have a detrimental effect on trust safety cultures; the CQC heard that rigid hierarchical structures prevent people from speaking up about potential safety critical incidents.'[9]

Recommendations arising from the report included the following:

'The national patient safety strategy must support the NHS to have safety as a top priority. Driven by the national director of patient safety at NHS Improvement, it should set out a clear vision on patient safety, clarifying the roles and responsibilities of key players, including patients, with clear milestones for deliverables. It should ensure that an effective safety culture is embedded at every level, from senior leadership to the frontline.[9]

'The National Patient Safety Alert Committee (NaPSAC) should oversee a standardised patient safety alert system that aligns the processes and outputs of all bodies and teams that issue alerts, and make sure that they set out clear and effective actions that providers must take on safety-critical issues.[9]

'CQC will use the findings of this report to improve the way we assess and regulate safety, to ensure that the entire NHS workforce has a common understanding of leadership and just culture, and the skills and behaviours necessary to make safety a priority'.[9]

NHS Improvement: the NHS patient safety strategy

Recommendations from HSIB and CQC reports have been incorporated in a new NHS patient safety strategy published by NHS Improvement in July 2019.[15] These include:

'Establishing a national patient safety alerts committee that will oversee a credentialing system and approve all alert issuers from Q2 2019/20 and ensuring that 100% are responded to and implemented or alternatives are in place from Q4 2019/20.'[15]

NHS England also intends to publish a definitive guide to '*who does what in relation to patient safety*'. This will be particularly helpful in determining which organisations are responsible for various aspects of patient safety oversight and delivery.

Although these proposed actions address some of our concerns over the implementation of patient safety alert guidance, we still have significant concerns.

CONCERN 1:

It is unclear whether the NHS is expected implement (and to continue to implement) all Patient Safety Alerts that have been published. There is also lack of clarity over the remit of the Patient Safety Team and the National Reporting Service in NHS Improvement and the criteria required to trigger the publication of a Patient Safety Alert. How will a risk be managed, after a Patient Safety Alert has been issued, and reports of death and serious harm continue to be received months and years after the date the Alert should have been implemented?

There were three types of patient safety alert that were issued by NHS Improvement and NHS England between December 2013 to October 2019. The definition of these three alert types are published on the NHS Improvement website.[16]

Warning alerts

'Typically issued in response to a new or under-recognised patient safety issue with the potential to cause death or severe harm. We aim to issue warning alerts as soon as possible after becoming aware of an issue and identifying that healthcare providers could take constructive action to reduce the risk of harm. Warning alerts ask healthcare providers to agree and coordinate an action plan, rather than to simply distribute the alert to frontline staff.'[16]

Resource alerts

'Typically issued in response to a patient safety issue that is already well-known, either because an earlier warning alert has been issued or because they address a widespread patient safety issue. Resource alerts are used to ensure healthcare providers are aware of any substantial new resources that will help to improve patient safety and ask healthcare providers to plan implementation in a way that ensures sustainable improvement. Highlighted resources will usually have been developed by national bodies, professional organisations or networks.'[16]

Directive alerts

'Typically issued because a specific, defined action to reduce harm has been developed and tested to the point where it can be universally adopted, or when an improvement to patient safety relies on standardisation (all healthcare providers changing practice or equipment to be consistent with each other) by a set date.'[16]

These definitions do not link with the current use of the patient safety alert compliance report, that indicates that NHS trust must comply with all types of alert.

These definitions indicate that NHS only **must** implement directive alerts. Warning alerts identify an issue so that healthcare providers **could** take action and resource alerts make healthcare providers **aware** of a new resource.

The number of directive alerts published each year has reduced considerably in recent times. The last one was published in November 2019 (*wrong selection of orthopaedic fracture fixation plates*).[17] There were no directive alerts published in 2018. One was published in 2017 concerning removal or flushing of lines and cannulae after procedures.[18]

Alerts published by the NPSA in 2002-2012 were considered directive at the time, however their current implementation status remains unclear, as do current safeguards that the NHS are expected to have in place to minimise these risks.

A publication from the Central Alerting System helpdesk team in September 2019, entitled *'The Introduction of National Patient Safety Alerts'*[19] announced that *'The National Patient Safety Alerting Committee (NaPSAC), which consists of representation from all organisations that issue safety information to the NHS, is working to ensure that all future national patient safety alerts set out clear and effective system-wide actions that providers must take on critical patient safety issues.*

'NaPSAC have developed and agreed common standards and thresholds for national patient safety alerts to align all organisations that issue national alerts. A new consistent format for national patient safety alerts has also been agreed by the committee.[19]

'Each alert issuer is now going through the process of reaching these common standards and thresholds and being assessed to ensure these are met via an accreditation process. Once accredited, alert issuers will use the new national patient safety alert template when issuing alerts.[19]

'NHS Improvement patient safety team is the first alerting body to go through the accreditation process. They have been accredited to issue national patient safety alerts for three years from July 2019. All alerts that are issued by NHSI Patient Safety will come through in the new format. The

safety messages of other issuers will come through in this format following successful accreditation.'[19]

The CAS Alert went onto to describe that: *'Alerts will have clear, effective actions, requiring senior oversight, that you must take on safety critical issues. The standards and thresholds agreed by NaPSAC will underpin the CQC inspection of national patient safety alerts and the potential for regulatory response for non-compliance. Responses to national patient safety alerts will still need to be made via the CAS system.'*[19]

New format patient safety alerts, based on the above, began to be issued by NHS Improvement from November 2019. The new format does not include any of the previous terms *'Warning, Resource or Directive'*, although definitions of the three previous types of alerts remain on the NHS Improvement website. There is insufficient information about the implementation requirements of the new format patient safety alerts on the NHS Improvement website.

It is assumed that the new format patient safety alerts are all now directive and not advisory. NHS Improvement should update their website and publications to make this clear and indicate that the previous alert types will not be used in the future. Clarification over implementation requirements of previous patient alerts published by NHS Improvement, NHS England and the National Patient Safety Agency is also required. It is also very difficult to find previous patient safety alerts published in 2019 before November on the NHS Improvement website. All previously issued alerts should be made easier to locate on the website.

The CAS alert announcing the new format patient safety alerts in September 2019 indicated that each alert issuer will use common standards and thresholds to produce patient safety alerts.

NHS Improvement issued *'Summary criteria for the management and creation of national patient safety alerts'* in May 2019.[20] This required the following:

- Governance arrangements are in place

- Processes for escalating issues with the potential to result in a national patient safety alert are in place

- Processes for developing and issuing a national patient safety alert are in place

- Quality assurance of the national patient safety alerts are in place.

In the summary criteria document, it states that *'national patient safety alerts should be in line with the statutory requirements on the issuing teams/bodies and 'remit' needs to be clearly understood externally as well as internally to avoid overlap between bodies.'*[20]

In our view the remit of the patient safety team and the National Reporting and Learning Service in NHS Improvement is not clearly documented to enable understanding externally.

When the NRLS and the National Patient Safety Agency, the predecessor of the current patient safety team, was established, their remit was to identify and act on all major risks to patient safety. When did the remit of the patient safety team and their patient safety alerts change to focus only on ' new and unrecognised' risks to patient safety?

Which organisation is now responsible for informing the NHS and co-ordinating action on known/wicked risks? Why are these risks no longer included as patient safety alerts? These known risks form the majority of the reports of death and serious harm sent to the NRLS each year.

Other statements in the summary criteria document include the following:

'Each issuing body needs to demonstrate clarity about how decisions are made to issue national patient safety alert within the scope of authority.'[20]

'The system includes checks that the proposed national patient safety alert meets NaPSAC agreed threshold of 'more likely than not one or more potentially avoidable deaths or disability in healthcare' in England each year.'[20]

The NRLS receives information about dozens of risks that have caused and are likely to continue to cause avoidable deaths or disability via the NRLS each year. What criteria is used to further select the risks chosen for the few patient safety alerts that are published?

The number of patient safety alerts published each year has reduced (Figure 1). AVMA is concerned that the number of patient safety alerts published by NHS Improvement annually, will continue to reduce in the future, in contrast to increasing number of deaths and serious harms reported to the NRLS.

The new summary criteria also do not cover risks where a patient safety alert was previously issued and where reports of death and serious harm continue to be received months and years after the date the alert should have been implemented. Current practice appears to be to archive these alerts, classify these risks as known/wicked and issue no further patient safety alerts or co-ordinate any further action on the majority of these risks.

<div style="background:#1a6b7a;color:white;padding:2px 8px;display:inline-block">RECOMMENDATION 1</div>

More information should be published by NHS Improvement concerning:

1. **Implementation requirements of new format national patient safety alerts and previous format patient safety alerts published by NHS Improvement, NHS England and the National Patient Safety Agency.**

2. **The current statutory requirements and scope of the patient safety team and National Reporting and Learning System. If this only includes new/unrecognised risks, when did this change and which organisation is now responsible nationally for publishing detailed data to identify and co-ordinate action on known/wicked risks?**

3. **The threshold required for the publication of a patient safety alert concerning a specific risk has been defined as *'more likely than not, one or more potentially avoidable deaths or disability in healthcare' in England each year.'*[20] The NRLS receives incident reports about dozens of risks that exceed this threshold each year. What criteria are used to further select the few risks chosen for patient safety alerts that are published by NHS Improvement?**

4. **Further clarity is required on how risks will be managed once a patient safety alert has been published and the risk can no longer be classified as 'new or unrecognised'. Will additional patient safety alerts be issued concerning the same risk, if evidence of harm continues to be reported? What other action will be taken to better manage these risks?**

<div style="background:#1a1a1a;color:white;padding:2px 8px;display:inline-block">CONCERN 2</div>

There is insufficient transparency concerning the identity of all major risks, including known/wicked risks to patient safety reported to the NHS National Reporting and Learning System (NRLS).

The NHS patient safety strategy states that patient safety alerts will be used to communicate *'new and unrecognised risks'* and that alerts are not an appropriate response for known/wicked risks[15]. This raises uncertainty over the status of previous alerts published by the National Patient Safety Agency and NHS England and how these types of risks will be managed.

It also raises a question of the purpose of the current NRLS and it's planned replacement. The current system receives over 2 million incident reports each year. However, it appears that these incidents are only now reviewed for 'new and unrecognised' risks, by NHS Improvement. In the past there was much more analysis and information for learning from the NRLS to identify the major risks at a national level. Regular publications such as observatory reports, themed reviews, and quarterly data summaries were available.[21-31] These reports provided both quantitative and qualitative (incident descriptions) data of incident reports on major risks at a level of detail suitable for learning.

Detailed NRLS analysis describing major risks has not been available since 2010. All that is available are publications providing the numbers and severity of incidents reported by NHS organisation in the secondary and community sectors each month. Every quarter, there is summary data of the total number of incidents reported, and by broad incident category types.[32]

- Access, admission, transfer, discharge (including missing patients)
- Clinical assessment (including diagnosis, scans, tests, assessment)
- Consent, communications, confidentiality
- Documentation (including records identification)
- Implementation of care and ongoing monitoring/review
- Infrastructure (including staffing, facilities and environment)
- Medication
- Patient accidents
- Treatment, procedures
- Any other category

There is also a NRLS commentary report that describes the numbers of reports received[33] but provides no detailed analysis or examples of the types of risks being identified, their trends or what safeguards should be in place to address these risks.

The information in these reports is insufficient for learning. Analysis coming from NRLS reports can change over time, and it is important that up-to-date information about all major risks (including known/wicked risks identified by previous patient safety alerts) is published regularly and available to the NHS, the public and organisations like AvMA to access. For example, the HSIB had to obtain a separate NRLS report to obtain more detailed information concerning the number of wrong route errors (never events) reported, which revealed that the number of these types of incidents had increased by 23% from 2016/17 to 2017/18[12].

Inadequate NRLS reports and the small number of patient safety alerts focused on 'new and unrecognised risks' (six alerts in 2017, nine in 2017 and five in 2019) currently provides a very poor return on investment in time, effort and expense of operating a national reporting system, and patient safety group in NHS Improvement.

A more transparent reporting system should be at the very centre of determining patient safety strategy and ensuring and providing assurance that major risks are being addressed. Regularly sharing details of actual risks reported, trend analysis and safeguards in place should be an essential component of any patient safety strategy.

RECOMMENDATION 2

The NRLS (and any successor systems) should regularly publish detailed information on all major risks identified by the reporting system at a suitable level for learning. This data should be cross referenced to recommended safeguards in practice (guidance from patient safety alerts) intended to minimise harm. Collectively this guidance forms national standards for patient safety.

There have been 137 patient safety alerts published in England since 2002. Many of these alerts identified and provided guidance on major risks from the NRLS. Some 75 of the alerts have now been archived and the NHS patient safety strategy raises uncertainty over the status of all previous alerts concerning risks now described as known/wicked risks. The new national patient safety improvement programme only addresses a very small number of these risks. How will risks outside the safety improvement programme be managed?

Although there is evidence that implementation of national patient safety guidance published in previous alerts has been poor in the NHS,[11 & 12] where is the evidence that the guidance in previously published alerts is not effective if implemented as intended and the guidance is no longer appropriate as stated in the NHS strategy?[15]

In the patient safety strategy[15] and in response to correspondence raising concerns over the strategy, NHS Improvement has made it clear that it is not in favour of a top down approach to identifying and managing known/wicked risks to patient safety. It is in favour of the collaborative 'bottom up' approach, where practitioners and organisation identify, prioritise and develop their own solutions to address risks to patient safety.[34]

The national patient safety improvement programme focusing on a small number of selected topics[15] will be delivered by the NHS patient safety collaboratives (PSCs).[35] This is a joint initiative, funded and nationally coordinated by NHS Improvement, with the 15 regional PSCs organised and delivered locally by the academic health science networks (AHSNs).

In a recent report reviewing the four years since PSCs were established in 2014, it was concluded that they had had very limited success with *'only a very few programmes*

having had national impact. This can be partly attributed to a lack of clarity about the fundamental purpose of the PSCs and the role they should play in delivering systematic quality improvement, including raising the profile of this work, sharing good practice, and collaborating and gathering evidence to support initiative.[36]

'PSCs adopted a variety of operating models and workstreams. The introduction of the three national workstreams in 2017/18 (safety culture improvement, earlier recognition of deterioration, and support for the maternal and neonatal programme) provided a clearer steer on what is expected of the PSCs and helped focus the initiatives under three main themes.[36]

'The PSCs' overall remit is not consistently understood by the PSCs themselves or by stakeholders in regional and local teams. The specification and contract for the PSCs must set this out, giving clarity on their scope, functions, minimum expectations, priorities and expected outcomes. This should help give PSCs a common understanding of what a 'collaborative' is and how this model can be used to effect change.'[36]

A systematic review of published evidence for the impact of quality improvement collaboratives concluded *'the evidence underlying quality improvement collaboratives is positive but limited and the effects cannot be predicted with great certainty. Considering that quality improvement collaboratives seem to play a key part in current strategies focused on accelerating improvement, but may have only modest effects on outcomes at best, further knowledge of the basic components effectiveness, cost effectiveness, and success factors is crucial to determine the value of quality improvement collaborative.'*[37]

An evaluation of a previous large-scale NHS patient safety collaborative initiative by the Health Foundation concluded that *'designing and implementing interventions to address these problems proved very challenging. Teams*

struggled to choose the right interventions – and right number of interventions – and many of the hazards and risks were too 'big and hairy' to be tractable to quality improvement methods based on plan-do-study-act (PDSA) cycles.'[38]

We are concerned that individual NHS trusts will not have the time and resources to develop unique solutions to known/wicked risks, previously identified in patient safety alerts.

Even if sufficient resources in local organisations were available this would create 'post code patient safety', where some trusts would have implemented safeguards to specific risks and others would not and different safeguards would have varying levels of effectiveness in preventing harm. As a national health service, there should be clearly defined national patient safety standards that patients should expect when receiving care in any NHS organisation.

Some known/wicked risks such as those that require new products from industry or the adoption of standardised information for patients and a treatment record book, e.g. the yellow book for anticoagulant treatment, can only successfully be undertaken at national level.

We do support the continued investigation of the patient safety collaborative model to develop evidenced based national solutions to some long-standing risks. However, the number of risks to be addressed in this way is very limited and the time taken to develop national solutions to individual risks may take years. This can never be the only method to address major risks to patient safety in the NHS.

Risks and guidance identified from previous patient safety alerts cannot be forgotten (an organisation 'losing its memory') or wait years for a few selected risks to be included within the national patient safety improvement programme.

We think that the original remit for patient safety alerts should be re-instated. Alerts should be used to communicate all types of risk to patient safety, not just new and unrecognised risks, alerts should once again contain materials to support NHS organisations implement guidance. This will help to minimise duplication of work by individual health care provider organisations and enable them to more effectively adopt and adapt alert guidance designed to safeguard patients from major risks. Information in these new alerts should be used to provide national standards for patient safety to prevent 'post code patient safety'.

RECOMMENDATION 3

The original remit for patient safety alerts should be reinstated. Alerts should be used to communicate all types of risk to patient safety, not just new and unrecognised risks. All alerts should once again contain materials to support NHS organisations to implement guidance.

All previous patient safety alerts should be regularly reviewed, linked to current NRLS data, other evidence and guidance. NHS Improvement should publish updated alerts to assist the NHS to continue to address these known risks. Information in these new alerts should be used to provide national standards for patient safety to prevent 'post code patient safety'.

CONCERN 4

Whilst the rate of compliance with patient safety alerts has improved since our previous reports, there still appears to be inadequate monitoring and regulation of compliance of primary as well as secondary and community sectors at national level.

Many of the alerts in our study had not been complied with significantly after the deadline. For example, there were six instances of non-compliance going back to deadlines in

2016, and 12 instances going back to 2017. Some trusts had several alerts which were significantly past the deadline for completion. For example, Dartford and Gravesham NHS Trust had five alerts they had not complied with by the deadline and Wye Valley had four. Yet, responses our FOI requests did not indicate that there had been any 'chasing up' or other action taken by the CQC or NHS Improvement. The CQC were not even able to tell us about regulatory action they had taken, if any, with regard to poor compliance with patient safety alerts. The CQC has no central database of non-compliance or action being taken with regard to non-compliance with alerts. This information is held at the local level. It is not clear whether any proactive action is taken to try to ensure trusts comply. Compliance is looked at when trusts are inspected, but we were not provided with any evidence that non-compliance results in any form of regulatory action by CQC (apart from a line in the CQC's response to our FOI request saying '*We can however, advise you that our enforcement team are aware of one such case*'). Neither did informal approaches both to NHS Improvement and CQC elicit any further information. It appears these bodies had no interest in gathering information they acknowledged they held even in order to help themselves understand how they were approaching this issue, let alone showing transparency and co-operation with the leading patients' charity focussed on patient safety.

The current alert compliance system operated by the Central Alerting System and NHS Improvement only provides information from NHS trusts in secondary and community care. There is no compliance information from primary care, and some of the patient safety alerts highlight important risks in this sector e.g. '*risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders*'.[39]

It is unclear what current checks or information is collected on alert compliance in primary care is undertaken or available from the CQC.

RECOMMENDATION 4

A more robust and proactive system of monitoring and regulating compliance with patient safety alerts in both primary, secondary and community sectors is required. The CQC should maintain a central database on alert compliance and actions they are taking to ensure compliance. The CQC (or NHS Improvement) should proactively 'chase' trusts and provider organisations who are late in complying and CQC should be seen to take regulatory action over non-compliance long past a deadline or non-compliance with multiple patient safety alerts.

References

1. Department of Health England. *An organisation with a memory*. 2000. Available at: https://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4098184. Accessed on 29.10.2019.

2. The National Reporting and Learning System. 2019. Available at: https://report.nrls.nhs.uk/nrlsreporting. Accessed on: 29.10.2019.

3. NHS Improvement. *National patient safety incident reports*. 2019. Available at: https://improvement.nhs.uk/resources/national-quarterly-data-patient-safety-incident-reports/. Accessed on: 29.10.2019.

4. Central alerting system. 2019. Available at: https://www.cas.mhra.gov.uk/home.aspx. Accessed on: 29.11.2019.

5. NHS Improvement. *Data on patient safety alert compliance*. 2019. Available at: https://improvement.nhs.uk/resources/data-patient-safety-alert-compliance/. Accessed on: 29.10.2019.

6. Care Quality Commission. *What we do*. 2019. Available at: https://www.cqc.org.uk/what-we-do. Accessed on: 29.10.2019.

7. Action against Medical Accidents. *Patient safety alert reports 2010 – 2014*. Available at: https://www.avma.org.uk/policy-campaigns/patient-safety/patient-safety-alerts/. Accessed on: 29.10.2019.

8. NHS Improvement. *Patient safety alert. Resources to support safer bowel care for patients at risk of autonomic dysreflexia*. 2018. Available at: https://improvement.nhs.uk/news-alerts/patients-at-risk-of-autonomic-dysreflexia/. Accessed on: 29.10.2019.

9. Care Quality Commission. *Opening the door to change*. 2019. Available at: https://www.cqc.org.uk/publications/themed-work/opening-door-change. Accessed on: 29.10.2019.

10. Care Quality Commission. *Health assessment framework*. 2019. Available at: https://www.cqc.org.uk/sites/default/files/20180628%20healthcare%20services%20kloes%20prompts%20and%20characteristics%20final.pdf. Accessed on: 29.10.2019.

11. Care Quality Commission. *Regulation 12. Safe care and treatment*. 2019. Available at: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment. Accessed on: 29.10.2019.

12. Healthcare Safety Investigation Branch. *Inadvertent administration of an oral liquid medicine into a vein.* 2018. Available at: https://www.hsib.org.uk/investigations-cases/inadvertent-administration-oral-liquid-medicine-vein/. Accessed on: 29.10.2019.

13. National Patient Safety Agency. *Patient safety alert. Promoting safer measurement and administration of liquid medicines via oral and other enteral routes*. 2007. Available at: https://webarchive.nationalarchives.gov.uk/20171030131255/http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=59808&p=3. Accessed on: 29.10.2019.

14. NHS Improvement. *Looking for content from the old National Patient Safety Agency (NPSA) website?* 2019 . Available at: https://improvement.nhs.uk/resources/learning-from-patient-safety-incidents/. Accessed on: 29.10.2019.

15. NHS Improvement. *The NHS patient safety strategy*. 2019. Available at: https://improvement.nhs.uk/resources/patient-safety-strategy/. Accessed on: 29.10.2019.

16. NHS Improvement. *Patient safety alerts*. Available at: https://improvement.nhs.uk/resources/patient-safety-alerts/. Accessed on 20.10.2019.

17. NHS Improvement. *Patient safety alert. Wrong selection of orthopaedic fracture fixation plates*. 2019. Available at: https://improvement.nhs.uk/news-alerts/wrong-selection-of-orthopaedic-fracture-fixation-plates/. Accessed on: 29.10.2019.

18. NHS Improvement. *Patient safety alert. Confirming removal or flushing of lines and cannulae after procedures*. 2018. Available at: https://improvement.nhs.uk/news-alerts/confirming-removal-or-flushing-of-lines-and-cannulae-after-procedures/. Accessed on 29.10.2019.

19. Medicines and Healthcare Products Regulatory Agency. *Alert from the Central Alerting System Helpdesk Team The introduction of National Patient Safety Alerts Alert ref: CHT/2019/001* Issued: 17/09/2019. Available at https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102890 Accessed 5.1.2020

20. NHS Improvement. *Summary criteria for the management and creation of National Patient Safety Alerts*. May 2019. Available at: https://improvement.nhs.uk/documents/6027/Credentialing_Criteria_Confirmed_May_2019_.pdf. Accessed 5.1.2020

21. National Patient Safety Agency. *Delayed diagnosis of cancer: thematic review*. March 2010. Available at: https://webarchive.nationalarchives.gov.uk/20171030131100/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=69894&p=2. Accessed on: 29.10.2019.

22. National Patient Safety Agency. *Anti-cancer medicines themed review*. October 2010. Available at: https://webarchive.nationalarchives.gov.uk/20171030125632/http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=75475. Accessed on: 29.10.2019.

23. National Patient Safety Agency. *Surgical safety can be improved through better understanding of incidents reported to a national database*. October 2009. Available at: https://webarchive.nationalarchives.gov.uk/20171030131110/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=63054&p=2. Accessed on: 29.10.2019.

24. National Patient Safety Agency. *Safety in doses*. September 2009. Available at https://webarchive.nationalarchives.gov.uk/20171030131111/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=61625&p=2. Accessed on: 29.10.2019.

25. National Patient Safety Agency. *Review of patient safety for children and young people*. June 2009. Available at: https://webarchive.nationalarchives.gov.uk/20171030131159/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=59864&p=3. Accessed on: 29.10.2019.

26. National Patient Safety Agency. *Patient safety observatory report 5. Safer care for acutely ill patients. Learning from serious incidents*. January 2007. Available at: https://webarchive.nationalarchives.gov.uk/20171030131157/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=59828&p=4. Accessed on: 29.10.2019.

27. National Patient Safety Agency. *Patient safety observatory report 4. Safety in doses*. January 2007. Available at: https://webarchive.nationalarchives.gov.uk/20171030131244/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=59822&p=4. Accessed on: 29.10.2019.

28. National Patient Safety Agency. *Patient safety observatory report 3. Slips, trips and falls in hospitals*. June 2007. Available at: https://webarchive.nationalarchives.gov.uk/20171030131246/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=59821&p=4. Accessed on: 29.10.2019.

29. National Patient Safety Agency. *Patient safety observatory report 2. With safety in mind. Mental health services and patient safety*. July 2007. Available at: https://webarchive.nationalarchives.gov.uk/20171030131155/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=59838&p=4. Accessed on: 29.10.2019.

30. National Patient Safety Agency. *Patient safety observatory report 1. Building a memory*. July 2005. Available at: https://webarchive.nationalarchives.gov.uk/20171030131106/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?entryid45=59797&p=4. Accessed on: 29.10.2019.

31. National Patient Safety Agency. *Quarterly data summaries*. 2007-09. Available at: https://webarchive.nationalarchives.gov.uk/20171030124701/http://www.nrls.npsa.nhs.uk/resources/type/data-reports/?p=4. Accessed on: 29.10.2019.

32. NHS Improvement. *NRLS number of incidents reported by quarter*. October – December 2018. Available at: https://improvement.nhs.uk/resources/national-patient-safety-incident-reports-27-march-2019/. Accessed on: 29.10.2019.

33. NHS Improvement. *NRLS national patient safety incident reports: commentary*. March 2019. Available at: https://improvement.nhs.uk/documents/5065/napsir_commentary_march_2019_final.pdf. Accessed on: 29.10.2019.

34. Cousins DH. *The new NHS patient safety strategy has a big hole in it*. August 2019. Response to correspondence from NHS Improvement. Available at: https://www.pharmaceutical-journal.com/opinion/correspondence/the-new-nhs-patient-safety-strategy-has-a-big-hole-in-it/20206882.article. Accessed on: 29.10.2019.

35. NHS Improvement. *Patient safety collaboratives*. 2019. Available at: https://improvement.nhs.uk/resources/patient-safety-collaboratives/. Accessed on: 29.10.2019.

36. NHS Improvement. *Patient safety collaborative. A retrospective review*. January 2019. Available at: https://improvement.nhs.uk/documents/3660/patient_safety_collaboratives.pdf. Accessed on: 29.10.2019.

37. Schouten Loes MT, Hulscher Marlies EJL, Everdingen Jannes JE Van, Huijsman Robbert, Grol Richard PTM. *Evidence for the impact of quality improvement collaboratives: systematic review* BMJ 2008; 336 :1491. Available at: https://www.bmj.com/content/336/7659/1491. Accessed on: 29.10.2019.

38. Health Foundation. *Safer clinical systems: evaluation findings learning from the independent evaluation of the second phase of the safer clinical systems programme*. 2014. Available at: https://www.health.org.uk/sites/default/files/saferclinicalsystemsevaluationfindings_fullversion.pdf. Accessed 29.11.2019.

39. NHS Improvement. *Patient safety alert. Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders*. 2018. Available at: https://improvement.nhs.uk/news-alerts/failure-to-obtain-and-continue-flow-from-oxygen-cylinders/. Accessed on: 29.10.2019.